IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	Hon. Robert. B. Kugler
This Document Relates To: *All Actions*	No. 19-md-2875 (RBK)

THIRD-PARTY PAYORS' REPLY BRIEF
IN SUPPORT OF MOTION FOR CLASS CERTIFICATION

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INTRODUCTION

In their motion for class certification, MSPRC and MADA demonstrated on behalf of the Third-Party Payors (the "TPPs") that class certification is appropriate under Rule 23(b)(3). A unitary class action is the most appropriate and efficient method of dealing with the TPPs' claims, all of which arise out of the Defendants' manufacture and sale of adulterated VCDs containing genotoxic impurities that are probable human carcinogens.

Unsurprisingly, in their Opposition to Plaintiffs' Motion for Class Certification of Third-Party Payors [ECF No. 2010] (the "Opposition" or "Opp."), Defendants ignore the common facts, and instead argue that it would be unmanageable to have such a large class action and that there are too many purported differences between TPPs. Those arguments are meritless—especially considering the alternative of hundreds, if not thousands, of individual TPP lawsuits, with the same core issue, litigated over and over again, draining judicial resources and risking conflicting results.

The proposed class action is superior and manageable, and common legal and factual issues predominate over any purported individualized issues. TPPs have strategically grouped together their claims by states that have similar laws. Further, TPPs can establish injury on a classwide basis because it was unlawful for the Defendants to sell adulterated VCDs. *See* 21 U.S.C. §§ 331, 351. All TPPs are entitled to a full refund of any money that they paid for the VCDs.

Defendants also argue that MSPRC and MADA are not typical and adequate class representatives based on purported differences between them and the proposed class. But the law is clear that factual differences do not defeat class certification if the claims of the named plaintiffs and putative class members involve the same conduct by the defendant, as is the case here.

[redacted]

[redacted]

Ultimately this is a prototypical case where class certification is warranted. All the claims are based on the same underlying conduct, and the proposed class meets the requirements of Rule 23(b)(3). The Court should certify the class.

ARGUMENT

I. TPPS HAVE SATISFIED THE PREDOMINANCE STANDARD

A. Common Legal Issues Predominate Over Individualized Issues

TPPs' approach under Rule 23(b)(3) is consistent with the approach taken by other courts that have grouped plaintiffs' state law claims and legal questions together for predominance purposes at the class certification stage. "When common questions of fact and law otherwise predominate, courts rarely deny certification simply because the class spans many states and asserts state-law claims." *In re Polyurethane Foam Antitrust Litig.*, 2014 WL 6461355, at *72 (N.D. Ohio 2014). To be grouped, state laws do not have to be identical; they just need to be similar enough that common issues predominate over individual ones, and no present and fundamental intra-class conflicts arise. Defendants argue that "these groupings are based on superficial legal analyses" that ignore "outcome-determinative legal distinctions within the proposed subclasses." Opp. at 8. That, however, is a gross mischaracterization. The substantive law of the jurisdictions covered by the TPP class and subclass, as set out in the grouping tables, present only minor differences that are similar enough to satisfy Rule 23(b)(3).[1] The classes and subclasses that TPPs

[1] *See, e.g., In re Pharm. Indus. Average Wholesale Price Litig.*, 252 F.R.D. 83, 93 (D. Mass. 2008) ("Differences among applicable state laws are not necessarily fatal to certification of a proposed class action."); *Klay v. Humana, Inc.*, 382 F.3d 1241, 1262 (11th Cir. 2004) ("[I]f a claim is based on a principle of law that is uniform among the states, class certification is a real possibility."); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 306 (D. Mass. 2021) ("The variety of state laws applicable to the EPPs' claims does not overwhelm predominance. The EPPs have provided charts compiling the state laws applicable to their antitrust and consumer protection

ask the Court to certify are based on the state-law groupings the Court has already adopted in its Orders on motions to dismiss and in The Special Master Report on Plaintiffs' Motion for Leave to Amend Master Complaints. ECF No. 1614. Thus, TPPs have satisfied Rule 23(b)(3)'s predominance requirement. *See* Pls.' Reply in Further Supp. of Their Mot. For Class Certification of Consumer Economic Loss Claims (the "EL Consumer Reply") at 20-23.

B. Common Factual Issues Predominate Over Individualized Issues

1. Third-Party Payors Can Establish Injury on a Classwide Basis

According to Defendants, TPPs cannot prove injury on a classwide basis on the theory that "the VCDs had substantial economic value to many patients, and by extension, their TPPs," because the VCDs "had different values depending on the levels of impurities they contained and the degree of therapeutic benefit experienced by each patient." Opp. at 9-10. As such, "a jury would have to make lot-by-lot and patient-by-patient determinations." *Id*. at 10.

Defendants' argument is meritless. The contaminated VCDs at issue have no economic value, measured (as is appropriate) at the point of purchase, and this absence of value is common to all TPPs. At the point of sale, TPPs paid or reimbursed for VCDs that were adulterated under 21 U.S.C. §§ 351(a)(1) and (a)(2)(B) (and analogous state laws), and thus were unlawful to sell, market, or distribute in the U.S., and consequently economically worthless. *See, e.g.*, ECF No. 1708 ¶¶ 4, 10-13, 60-73, 408, 421-24. TPPs were economically injured by paying for a worthless drug for their beneficiaries. *See, e.g.*, *id.* ¶¶ 68, 72.

TPPs' common monetary injury resulted from Defendants' failure to provide the benefit for which TPPs bargained. An injury based on a benefit-of-the-bargain theory turns on the nature of the

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claims and have identified the substantial similarities among those laws."). In any event, Defendants' arguments as to the makeup of the groupings isn't a basis to deny class certification; the Court and amend the groupings. *See* EL Consumer Reply at 22 n.49.

bargain itself. Here, in return for the purchase price paid to Defendants, TPPs' insureds were supposed to gain the benefit of purchasing the generic equivalent of Diovan, a therapeutically equivalent, unadulterated, and regulatorily compliant valsartan generic drug—as Defendants warranted (e.g., non-contaminated and originating from cGMP compliant manufacturing facilities or processes). *See, e.g.*, ECF No. 1708 ¶¶ 404-27, 430-31, 433, 437-40, 443, 446, 448. But TPPs' insureds did not receive such a product. They received worthless drugs that were contaminated and non-cGMP compliant.

The Eleventh Circuit's opinion in *Debernardis v. IQ Formulations LLC* is instructive. 942 F.3d 1076 (11th Cir. 2019). There, the Eleventh Circuit accepted the plaintiff's argument that a product that was illegal to sell under the Federal Food, Drug, and Cosmetic Act was economically worthless because Congress had essentially legislated as much by making adulterated drugs illegal to commercialize in the U.S.[2] So it is here. The VCDs were not generic equivalents, were adulterated and non-compliant with cGMPs, and were worthless. *See, e.g., In re Gerber Probiotic Sales Pracs. Litig.*, 2013 WL 4517994 (D.N.J. 2013) (plaintiffs did not get the benefit of the bargain when they purchased infant formula that didn't have the qualities defendants had promised, despite defendants' arguments that the formula still provided some "benefit"); *Blue Cross Blue Shield Assoc. v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531 (E.D. Pa. 2019).

Further, even if a drug containing genotoxic impurities is medically efficacious, it cannot create a benefit-of-the-bargain, because consumers and TPPs never bargained for the contaminants. For example, in *Blue Cross Blue Shield*, third-party payor plaintiffs sought damages

[2] Citing *Debernardis*, the Court wrote at the motion to dismiss stage: "This Court finds that contaminated drugs are economically worthless at the point of sale by virtue of the dangerousness caused by their contamination, regardless [of] whether the sold VCDs actually achieved the medical purpose of lowering blood pressure." ECF No. 775 at 20. The Court further stated that "contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for." *Id.*

because they paid for a drug that was warranted as compliant with cGMPs, when in fact it was not. 417 F. Supp. 3d at 554. The court rejected defendants' arguments that the cGMP violations did not have an impact on the drug itself and found that noncompliance with cGMPs could plausibly have rendered the products worthless. *Id.* at 554-55. Here, the evidence demonstrates that the cGMP violations resulted in genotoxic impurities and worthless drugs. There is no reason to conduct the individualized, retrospective post-sale inquiry into their value that Defendants envision.

Defendants next argue that TPPs cannot prove classwide injury because "some TPPs did not pay for VCDs and others would have had to pay *more* money for VCD alternatives." Opp. at 10. According to Defendants, "the key question" is "would the TPPs have paid less for the medication (or nothing at all) if they had known 'the truth.'" The first issue is easily dispensed with. Every TPP class definition only includes TPPs who paid for VCDs. *See* ECF No. 1747-2. If a TPP did not pay for VCDs, it is defined out of the class.

Second, the potential cost of "VCD alternatives" is irrelevant. Adulterated drugs cannot be legally sold. Since the VCDs at issue are economically worthless, TPPs are entitled to recover the money they paid for them. Under the UCC, "[w]here . . . the buyer rightfully rejects or justifiably revokes acceptance then with respect to any goods involved . . . the buyer may cancel and . . . recover[] so much of the price as has been paid." *See, e.g.*, 11 M.R.S. § 2-711(1) (Maine's UCC); *see also* 11 M.R.S. § 2-714(2) ("The measure of damages for breach of warranty is the difference at the time and place of acceptance between the value of the goods accepted and the value they would have had if they had been as warranted"—which in this case is zero.).

The cases Defendants cite do not support their position. In *Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401, 411-12 (11th Cir. 2011), the plaintiffs were seeking a refund because the drugs had "undisclosed dangerous side effects"— not because the drugs were

adulterated and contaminated with unapproved genotoxic impurities. The court found no support for plaintiffs' argument that "the potential of a drug to cause harmful side effects, in the abstract, renders a drug per se unmerchantable." *Id.* at 411. But here, 21 U.S.C. § 331 makes clear that contaminated and mislabeled drugs are *per se* unmerchantable.

Additionally, *In re Actiq Sales and Marketing Pracs. Litigation*, 307 F.R.D. 150, 171 (E.D. Pa. 2015) is not a contaminated drug case—it is premised on drug manufacturers improperly promoting the Actiq drug to doctors, which caused TPPs to pay for additional prescriptions. 307 F.R.D. at 170. In that context, the court found it "relevant to consider how TPPs varied, or could have varied, their coverage decisions." *Id.* at 171. "For example, those TPPs who approved payment after completing patient-specific prior authorization procedures cannot then claim that their payment resulted from inequity." *Id*. None of that remotely applies in this case. The VCDs were adulterated, and thus unlawful for sale under 21 U.S.C. §§ 331, 351. More so, TPPs had no knowledge of the contamination. As such, TPPs are entitled to a full refund of all monies paid.

2. TPPs Can Show Reliance on Manufacturer Defendants' Statements

Defendants also argue that TPPs cannot "satisfy Rule 23(b)(3)'s predominance requirement because of the need for individualized reliance inquiries to address their claims for fraud, breach of express warranty and (under many states' laws) consumer protection violations." Opp. at 12. Defendants argue that reliance cannot be established because many TPPs adopt formularies prewritten by a PBM, and therefore did not rely on Defendants' misrepresentations. Opp. at 13. As outlined in TPPs' brief, PBMs are agents for TPPs and their P&T Committees. ECF No. 1749 at 4. TPPs and their PBMs reasonably expect that generic prescription drugs listed in the Orange Book can be included in their formularies and qualify for reimbursement because they are legally compliant in terms of pharmaceutical equivalence, therapeutic equivalence, or

bioequivalence, or are otherwise the same as their RLD counterparts. *Id.* TPPs permitted the VCDs to be included on their formularies in reliance on Defendants' misrepresentations that their VCDs were pharmaceutically and therapeutically equivalent to the RLDs; satisfied all compendia, quality, purity, and other requirements; complied with all cGMPs; and were safe for consumption. *Id.* at 5. That is fundamental.

Defendants next argue that P&T Committees consider a "host of factors in deciding which medication to cover" that vary by "Committee, raising daunting individual reliance issues." Opp. at 12. Defendants argue that "P&T Committees rarely consider multi-source, generic medications on a manufacturer-by-manufacturer basis." Opp. at 13.

As outlined in Plaintiffs' brief, reliance can be established when there is "fraud on the market" or when common evidence will show that all class members would have behaved similarly under the circumstances—such as "through legitimate inferences based on the nature of the alleged misrepresentations at issue." ECF No. 1748 at 71-72 (citing *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 610-611 (3d Cir. 2012); *CGC Holding Co., LLC v. Broad & Cassel*, 773 F.3d 1076, 1089-90 (10th Cir. 2014); *Klay*, 382 F.3d at 1259; *Ge Dandong v. Pinnacle Performance Ltd.*, 2013 WL 5658790, at *10 (S.D.N.Y. 2013)). TPPs can easily establish an inference of reliance based on common circumstantial evidence. Indeed, the Court has already made this finding. *See* ECF No. 775 at 14 ("plaintiffs had no choice but to 'rely'" on Defendants' representations). TPPs and their agents were not aware, nor could they have been aware through reasonable diligence, that the VCDs contained NDMA/NDEA or were made in a non-cGMP compliant manner. The Manufacturers' identification of the drug as valsartan-containing informed TPPs that the drug was approved as a generic of the Orange Book formulation and was chemically and therapeutically equivalent to DIOVAN and/or EXFORGE, a representation upon which TPPs and/or their agent

PBMs justifiably relied. It's irrelevant that P&T Committees or PBMs supposedly consider a host of factors in setting up their formularies. And if not, what the TPPs and their agents relied on would still be a common question.

3. TPPs Have Met Their Burden to Show Classwide Damages

Defendants argue that TPPs cannot prove classwide damages on the theory that the VCDs were not "categorically" worthless; alternative therapies vary in price; and the price TPPs paid does not reflect the ultimate cost due to certain pre-and post-sale adjustments. *See* Opp. At 14-16. Once again, none of this is relevant, and no individualized inquiry is required because TPPs are entitled to a full refund of the money they paid for economically worthless VCDs.

Moreover, the law recognizes that damages may be estimated by an aggregate damages model. *See, e.g.*, *In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust. Litig.*, 967 F.3d 264, 271 (3d Cir. 2020); *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 2019 WL 4751883 (E.D. Pa. 2019); EL Consumer Reply at 14. [redacted] Point-of-sale or "full refund" damages are the appropriate measure of damages because the economic injury occurred at the point of sale when TPPs paid or reimbursed for their insureds' VCDs.[3] [redacted]

[3] *See, e.g.*, *Steroid Hormone Prod. Cases*, 181 Cal. App. 4th 145, 150-159 (2010) (approving full refund damages model where supplements were contaminated finding "in this case [plaintiff] does not put valuation at issue when he alleges that he bought a product that was illegal to sell or possess."); *In re Amla Litig.*, 282 F. Supp. 3d 751, 756, 767 (S.D.N.Y. 2017); *Krueger v. Wyeth, Inc.*, 2011 WL 8971449, at *2 (S.D. Cal. 2011) (approving full refund model despite evidence that doctors continued prescribing the drug and that plaintiff continued taking the drug even after becoming aware of health risks); *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 524 (6th Cir. 2015) ("Whether purchasers were nevertheless satisfied with Align does not affect the propriety of a full-refund damages model.").

[redacted] However, any such offsets are Defendants' burden to prove at trial and do not defeat class certification. *See Allen v. Holiday Universal*, 249 F.R.D. 166, 194-95 (E.D. Pa. 2008) (granting class certification despite offsets); *see also* EL Consumer Reply at 12, 18. [redacted] *See* EL Consumers' Reply at 36-38. Thus, 'identification' and 'exclusion' issues go to ascertainability, not to reliability of damages.

II. TPPs' CLASS PROPOSAL MEETS THE SUPERIORITY/ MANAGEABILITY REQUIREMENTS OF RULE 23(b)(3)

Defendants' superiority and manageability arguments are unfounded and substantially similar to the arguments that they raise in their Opposition to the Consumer Brief. ECF No. 2008. For that reason, TPPs fully incorporate Section II. A-B of the EL Consumer Reply into this reply. TPPs also note that courts have consistently certified litigation classes of TPPs with multiple state law claims and have found Rule 23(b)(3)'s superiority element to be satisfied.[5]

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[4] [redacted]

[5] *See, e.g., In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 576 (S.D.N.Y. 2021) ("[W]hatever difficulties in managing this class action are dwarfed by the extraordinary

III. MSPRC AND MADA ARE ADEQUATE AND TYPICAL THIRD-PARTY PAYOR CLASS REPRESENTATIVES

Defendants rely on multiple theories to argue that the named TPP Plaintiffs are not typical or adequate class representatives. They argue that MSPRC is "only" an assignee, that its claims arise from Medicare Advantage Plans ("MAO"), that it's not in the business of providing healthcare, and that MADA purportedly does not know enough about its claims. But by focusing narrowly on purported distinctions between the named TPP Plaintiffs and the class, Defendants miss the big picture. It is well established law in this circuit that:

> The typicality inquiry here centers on whether the named plaintiff[s'] individual circumstances are markedly different or . . . the legal theory upon which the claims are based differs from that upon which the claims of other class members will perforce be based. **The criterion acts as a bar to class certification only when "the legal theories of the named representatives potentially conflict with those of the absentees.**" **If the claims of the named plaintiffs and putative class members involve the same conduct by the defendant, typicality is established regardless of factual differences.**

Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc., 259 F.3d 154, 183-84 (3d Cir. 2001), *as amended* (Oct. 16, 2001) (cleaned up) (emphasis added). Defendants never suggest that there is a potential conflict between the named TPPs and the class members.

The claims of the named TPP Plaintiffs and the class arise out of the same conduct—the

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difficulty (if not practical impossibility) of bringing the likely thousands of individual cases against Defendants if a class were not certified . . . Defendants argue that the differences in state law preclude a finding of superiority, as individual actions would better address the varying statutes. However . . . that argument does not preclude certification."); *In re Zetia (Ezetimibe) Anti-trust Litig.*, 2020 WL 5778756, at *28 (E.D. Va. 2020), *report and recommendation adopted*, 2021 WL 3704727 (E.D. Va. 2021) ("potential variations among state laws will not render the case unmanageable. Thus, as courts consistently find in such cases, EPPs have satisfied the superiority requirement."); *In re Flonase Anti-trust Litig.*, 284 F.R.D. 207, 234 (E.D. Pa. 2012) ("both fairness and efficiency dictate that I certify the class in this case; otherwise, the numerous individual class members would be forced to file suit individually, producing numerous identical issues in each case that would waste judicial resources and leave all parties vulnerable to unfair inconsistencies"); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1, 39 (E.D.N.Y. 2020) ("EPPs have shown that litigating this case as a class is superior to other methods of adjudication. None of the factors listed in Rule 23(b)(3) counsels against certification.").

Defendants' manufacture and sale of VCDs containing genotoxic impurities that are probable human carcinogens. As such, the named TPP Plaintiffs have met the "low threshold for satisfying both requirements" of typicality and adequacy. *Newton*, 259 F.3d at 183 (collecting cases). Below, TPP Plaintiffs address the specific arguments on adequacy and typicality.

A. TPP Plaintiffs' Standing is Typical of the Class and They Have Adequately Pled Injury

Defendants argue that the named TPP Plaintiffs are inadequate class representatives on the theory that "they lack Article II standing" because "their claims are based solely on the argument that . . . the sale of 'adulterated' or 'misbranded' products [are] worthless." Opp. At 20. According to Defendants, the "TPP plaintiffs cannot show injury in fact because they have not provided any evidence that they actually lost money." *Id.* Defendants' argument fails for several reasons.

First, Defendants' argument is misplaced at the class certification stage, as it would apply equally to all members of the TPP class.[6] *Harnish v. Widener Univ. Sch. Of L.*, 833 F.3d 298, 305 (3d Cir. 2016) ("[E]vidence as to an issue or element need not be produced at class certification where the very nature of the issue or element guarantees that all class members' claims will 'prevail or fail in unison.'"). Second, as a matter of law, under 21 U.S.C. § 331, one is prohibited from introducing "into interstate commerce" any "adulterated or mislabeled" drug, making the Defendants' VCDs worthless. Third, the TPP Plaintiffs have submitted ample evidence that such drugs are in fact worthless. [redacted]

[6] For that reason, Defendants' reliance on *McNair v. Synapse Grp. Inc.*, 672 F.3d 213 (3d Cir. 2012) is inapposite. There the named plaintiffs purported to bring a class action for injunctive relief on behalf of a magazine's customers—but the named plaintiffs weren't current customers. *Id.* at 224-226. As such, the court found they lacked standing to represent the class. Here, there is no appreciable difference between the named TPP Plaintiffs and the proposed class members—all purchased worthless VCDs, and Defendants' defenses apply equally to the proposed class and named TPP Plaintiffs.

[redacted]

B. Proposed TPP Class Representatives Satisfy the Remaining Requirements

1. MSPRC Meets the Requirements of Adequacy and Typicality

Defendants argue that MSPRC isn't an adequate or typical class representative on three separate theories. Opp. At 21-23. All are without any basis. First, Defendants argue that MSPRC's mere "status as an assignee, rather than a true TPP," precludes it from acting as a class representative on the theory that there would need to be "fact-intensive inquiries" into the validity of the assignments. Opp. At 21. But a plaintiff's "status as an assignee [] does not prevent it from [] representing the class." *In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47, 53-54 (D. Mass. 2013) (citing *In re Vitamin C Antitrust Litig.*, 279 F.R.D. 90, 102 (E.D.N.Y.2012)); *Teva Pharms. USA, Inc. v. Abbott Lab's*, 252 F.R.D. 213, 226 (D. Del. 2008) ("[T]he Third Circuit has not adopted the position" that assignees cannot serve as class representatives.)

In any event, the "presence of individual questions . . . does not mean that the common questions of law and fact do not predominate over questions affecting individual members as required by Rule 23(b)(3) or that the representative's claims are not typical." *Eisenberg v. Gagnon*, 766 F.2d 770, 786 (3d Cir. 1985). Here, any individual questions as to the validity of the assignments would be dwarfed by the common questions affecting the class members. *See* ECF No. 1749 at 12 (listing 11 common questions of law or fact). The supposed defense only relates to one of the three MSPRC assignors, and "there is no sound reason why this court cannot order separate hearings on that particular issue." *Dura-Bilt Corp. v. Chase Manhattan Corp.*, 89 F.R.D.

[7] To be clear, TPPs continue to maintain that the VCDs were worthless. [redacted] Defendants cannot argue the opposite, i.e., that the VCDs were worth 100% of the value paid, which essentially is the argument they must make to support their theory that there was "no injury."

87, 98 (S.D.N.Y. 1981). Further, even assuming arguendo that the assignment was to be found invalid (which MSPRC does not concede), SummaCare would still remain a member of the proposed class, and MSPRC would still have standing as class representative by virtue of its other assignments, which are not governed by Ohio law.

Second, Defendants argue that MSPRC's purported "business of filing lawsuits" makes it an inadequate class representative. Opp. At 22. As support for this theory, which runs contrary to well-established Third Circuit law permitting assignees to bring claims, Defendants rely on *MAO-MSO Recovery II, LLC v. State Farm Mut. Auto. Ins. Co.*, 2018 WL 6634324, at *1 (C.D. Ill. 2018). But that court's ruling does not get Defendants very far, especially when viewed in context.

In *State Farm*, the plaintiff brought a class action suit as an assignee of an MAO. The limited issue before the court was the plaintiff's motion to quash a subpoena asking for communications between the plaintiff and the assignors. After noting that the plaintiff was not an MAO, but brought its claims as an assignee, the court ordered the plaintiff to produce the communications because the "***relationship*** of Plaintiffs to [the] assignees is directly relevant to whether they are appropriate class representatives." *Id.* at *5 (emphasis added). In other words, the court granted the requested discovery to probe the validity and scope of the assignments under the liberal relevance standard of Rule 26(b)(1). The court was not ruling on a motion for class certification, and it did not hold as a general rule that a plaintiff must be in the same business as the proposed class to serve as a class representative—as Defendants claim here.

Defendants also argue that MSPRC can't serve as a class representative on the theory that its "lawsuits generally target the very industry it now wants to represent." Opp. At 22. But that is legally wrong[8] and factually incorrect. While related entities of MSPRC have sued *automobile* and

[8] Defendants misstate the holding in *Glictronix Corp. v. Am. Tel. & Tel. Co.*, 603 F. Supp. 552,

first-party property insurers, neither MSPRC nor those related entities routinely sue *health insurers*, which are the entities that make up the bulk of the proposed class.

Third, Defendants argue that MSPRC's claims "are not typical of other TPP's" on the theory that its claims "arise" from MAO plans. Opp. At 23. But Defendants overstate the "typicality" requirement of Rule 23(a)(3) and ignore the makeup of the class. As demonstrated above, typicality is a low threshold. "[E]ven relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories or where the claim arises from the same practice or course of conduct." *Newton*, 259 F.3d at 183-84. Here, the legal theories are the same and arise out of the same course of conduct—Defendants' manufacture and sale of worthless VCDs that were tainted with a carcinogen and that didn't adhere to GMP. In any event, the class definition includes all "TPPs in the United States and its territories and possessions that . . . paid any amount of money for a valsartan containing drug . . . ." Included in that definition are MAOs, some of which didn't assign their claims to MSPRC. As such, *even if Rule 23 required identical claims and defenses* (it doesn't), MSPRC is still typical of the class.

2. MADA Meets the Requirements of Adequacy and Typicality

Defendants argue that MADA is not an adequate or typical class representative on the theory that it has "little actual knowledge of the claims being asserted." Opp. At 23. Specifically, they claim MADA's corporate representative, Tom Brown, was "generally uninformed about how much was paid by MADA for VCDs or the process by which MADA's liability for VCDs is

586 (D.N.J. 1984). Opp. at 22. That case does not stand for the general proposition that "named plaintiff cannot adequately represent its rivals," as Defendants claim. *Id*. (internal quotation omitted). Rather, it stands for the proposition that where the "interests [of the named plaintiff and proposed class] are adverse to one another" *because they are rivals*, then the named plaintiff is not an adequate representative. Here, Defendants have made no attempt to show that MSPRC's interests are adverse to that of the other TPPs health insurers that make up the proposed class.

calculated." *Id*. But Defendants overstate the level of engagement and knowledge required from a class representative, and they downplay the knowledge and engagement Mr. Brown demonstrated.

The two cases Defendants rely on not only fail to support Defendants' position, they actually show that Mr. Brown was sufficiently knowledgeable and engaged to make MADA an adequate representative under Rule 23(a)(4). *See* Opp. At 23-24 (citing *Shiring v. Tier Techs., Inc.*, 244 F.R.D. 307, 315-316 (E.D. Va. 2007) and *Kirkpatrick v. J.C. Bradford & Co.*, 827 F.2d 718, 727 (11th Cir. 1987)). The court in *Shiring* was clear that it is only in the "securities fraud context" where "the adequacy inquiry must be particularly searching," so that the "plaintiff [must] demonstrate[] that he understands the action in which he is involved and, notably that this "understanding [is] not . . . limited to derivative knowledge acquired solely from counsel." 244 F.R.D. 307, 315-316 (E.D. Va. 2007). That is because the Private Securities Litigation Reform Act (PSLRA) was "intended to empower investors so that they, not their lawyers, control securities litigation." *Id*. at 315-316. In contrast, in a non-PSLRA case, such as *Kirkpatrick,* "adequate class representation generally **does not** require that the named plaintiffs demonstrate to any particular degree that individually they will pursue with vigor the legal claims of the class." 827 F.2d at 727 (emphasis added). The representative must only have sufficient knowledge and involvement "to protect the interests of the class against the possibly competing interests of the attorneys." *Id.* at 727. The named plaintiffs cannot "'have abdicated their role in the case beyond that of furnishing their names as plaintiffs,' [so that] the attorneys, in essence, are the class representative." *Id.*

This lawsuit is not under the PSLRA; there is no heightened knowledge standard. Mr. Brown was not required to have memorized the total amount MADA paid for VCDs or to be familiar with specific details of how liability is calculated. What matters is that MADA has not

"abdicated [its] role in the case"—and it certainly has not. *Kirkpatrick*, 27 F.2d at 727. Mr. Brown demonstrated at his deposition that MADA was knowledgeable and involved in the litigation.

Mr. Brown testified that he reviewed and familiarized himself with all 48 topics and subtopics contained in Defendants' Amended Notice of Deposition to MADA, and that he had prepared for his deposition by meeting with counsel and reviewing documents on his own. Brown Dep. 19:12-17; 21:12-22:21; 29:1-12; 30:21-31:20. He also had a good understanding of MADA's economic loss claims and the TPP class, and when asked what MADA "hope[d] to get out of this lawsuit," he responded: "[r]eimbursement for the cost of the medications that were contaminated and recalled . . . ." *Id.* at 38:13-18; 36:12-18; 279:3-280:3. He also testified that he provided information for MADA's Plaintiff Fact Sheet and that he assumed the information he gave the attorneys would be used in drafting the complaint. *Id.* at 45:23-46:3; 59:12-60:20. That level of knowledge and engagement demonstrates that MADA meets Rule 23's adequacy requirements.

Defendants also argue that MADA was not an adequate or typical class representative on the theory that MADA did not itself review any representations from any defendant in this case about valsartan, and instead relied upon a formulary provided by Anthem Health Plans of Maine, Inc. ("Anthem"). Opp. at 23. But that wouldn't make a class representative inadequate,[9] and in any event, Anthem is MADA's contract administrator and agent. As Mr. Brown testified, MADA, through Anthem, relied on Defendants' representations that therapeutically equivalent VCDs were being purchased when choosing to include VCDs on MADA's formulary. Brown Dep. 101:25-102:6; 53:13-16; 96:20-97:5. The fact that MADA relied on Defendants' misrepresentations through its agent does nothing to weaken MADA's claims or its adequacy as a class representative.

[9] Defendants cite to *In re Kosmos Energy Ltd. Sec. Litig.*, 299 F.R.D. 133, 145 (N.D. Tex. 2014) for the proposition that the court should apply a "rigorous adequacy review," but that was a securities litigation case that was subject to the strict requirements of PSLRA.

IV. TPPS HAVE SHOWN THAT THE CLASS IS ASCERTAINABLE

A. Identifying the TPP Class is Administratively Feasible

Defendants argue that TPPs' proposed class is unascertainable on the theory that there is no way easy way to identify the TPP at-risk payors. Opp. At 27. Specifically, they claim that pharmacy claims data do not identify the TPP at-risk payors and that PBM data often do not identify the at-risk payors when the TPP has not contracted directly with the PBM. Opp. 26-27. According to the Defendants, one would have to engage in individualized fact-finding or "mini trials" to identify the at-risk payors, which Defendants claim would be administratively unfeasible, and thus would make the class unascertainable.[10] *Id.* at 25. Defendants are wrong.

[redacted]

For that reason, even if retail pharmacies do not have records that show the identities of

[10] Defendants cite to *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583 (3d Cir. 2012) to support their argument that the TPP class would require individualized fact finding or mini trials, but in *Marcus*, a class action over defective tires, there was no way to identify the class members. The tires were "made in Germany by a different company and BMW [didn't] maintain a parts manifest." *Id.* at 594 (internal quotations omitted). In other words, there simply weren't enough records to identify the class members. But that's not the case with the VCDs. As will be shown below, the data are readily available and concentrated in the hands of the pharmacies and PBMs.

the at-risk TPPs as Defendants claim (something that TPPs don't concede), the at-risk TPPs can still be identified with the PBM data. [redacted] And were there any doubt as to the adequacy of the records (there isn't), the Third Circuit has made clear that "Plaintiff need not, at the class certification stage, demonstrate that a single record, or set of records, conclusively establishes class membership." *City Select Auto Sales Inc. v. BMW Bank of N. Am. Inc.*, 867 F.3d 434, 441-42 (3d Cir. 2017). It is sufficient that "thousands of pages of contracts, driver rosters, security gate logs, and pay statements, as well as testimony from a dozen class members," plus affidavits, exist. *See, e.g., Hargrove v. Sleepy's LLC*, 974 F.3d 467, 470 (3d Cir. 2020). [redacted]

Lastly, Defendants argue that the ascertainably element has not been met on the theory that "plaintiffs have merely created vague assurances that a class is ascertainable." Opp. at 25. In support of that argument, they cite three cases—but all three are inapposite. In *Vista Healthplan, Inc. v. Cephalon, Inc.*, "the record before [the court] contain[ed] no evidence as to whether other

[11] [redacted]

pharmacies kept reliable records of this same type of patient data over that time period," and the plaintiffs' expert testified that "he was unaware of any such records." 2015 WL 3623005 at *10 (E.D. Pa. 2015). Thus, the court found that "Plaintiffs have failed to present evidence of a reliable 'mechanism for determining whether putative class members fall within the class definition.'" *Id.* That is not the case here. [redacted]

In *In re Wellbutrin XL Antitrust Litig.*, plaintiffs' experts merely offered "conclusory statements" that there were "administratively feasible method[s] [] for identifying which PBMs and consumers are in the class," but "[n]either expert [] examined or analyzed these pharmaceutical records." 308 F.R.D. 134 (E.D. Pa. 2015). [redacted] Additionally, the expert had only analyzed four sample transactions, two of which defendants challenged as "wrong." *Id.* at 167. [redacted]

B. The TPP Class Definition Is More Than Adequate

Defendants argue that the TPP class is not ascertainable on the theory that the class description does not include a detailed definition of what is a TPP. Opp. at 27. But there is no

requirement that a class description include a dictionary definition of its terms.[12]

In any event, Defendants' argument rings hollow—especially considering that Defendants are *drug manufacturers, drug distributors, and pharmacies*. As Defendants are aware, there are two parties that potentially pay for drugs that are consumed by end-users. There are the consumers who consume the drugs (and sometimes pay all or part of a drug purchase price) and then there are the third-party payors (a/k/a "TPPs") who don't consume the drugs, but pay for all or a portion of their cost. As the TPPs stated in their motion for class certification, typically "TPPs are health care benefit providers, such as an employer's insurance company or a health and welfare plan providing health care benefit to employees or beneficiaries." ECF No. 1749 at 2. But if a downstream entity, such as a physical office or healthcare provider, is at risk to pay for a consumer's VCDs, then yes, they too can be considered TPPs. There's no contradiction. In any event, courts routinely approve classes that include TPPs, and administrators have no trouble identifying the TPPs.[13]

CONCLUSION

For the reasons stated in the TPPs' opening brief, as well as those above, the Court should: (a) certify the classes pursuant to Fed. R. Civ. P. 23(a) and (b)(3) cited in ECF No. 1747-2; (b) appoint Jorge A. Mestre and Gregory P. Hansel as Class Counsel pursuant to Fed. R. Civ. P. 23(g); and (c) appoint the MSPRC and MADA to serve as the TPP Class Representatives.

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[12] Defendants cite to one case to support their theory that Plaintiffs needed to include a definition of a TPP in the class description. Opp. at 27. That case says nothing of the sort. In *Martinez v. Equifax Inc.*, the proposed class definition included "(1) all persons who disputed an Equifax credit report and (2) where Equifax failed to apply proper and appropriate FCRA procedures." 2016 WL 226639, at *1 (D.N.J. 2016). Unsurprisingly, the court found that the second prong lacked reference to objective criteria so that there was no administratively feasible mechanism for determining whether class members fall within the class definition. *Id.* at *3. That class was not rejected because of a purported failure to define "Equifax" or "FCRA," as Defendants suggest by citing the case.

[13] *See, e.g.*, E. Miller Decls., *attached as* Exhibit A ¶¶ 20-31, Exhibit B ¶¶ 7, 15, Exhibit C ¶¶ 12-19, Exhibit D ¶¶ 8, 11, Exhibit E ¶¶ 19-26; L. Young Decl., *attached as* Exhibit F ¶¶ 14-15 (declaration coversheets and attached exhibits removed for clarity).

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Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of May 2022, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. (There are no redactions in this brief.)

/s/ *Gregory P. Hansel*
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